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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/714,040

11/15/2000

Paul J. Carter

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5212

7590 04/05/2007
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Minneapolis, MN 55402-0903

EXAMINER

BLANCHARD, DAVID J

ART UNIT	PAPER NUMBER
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1643

MAIL DATE	DELIVERY MODE
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04/05/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action
Before the Filing of an Appeal Brief**

Application No.

09/714,040

Applicant(s)

CARTER, PAUL J.

Examiner

David J. Blanchard

Art Unit

1643

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 16 March 2007 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 3 + 1 months from the mailing date of the final rejection.
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

NOTICE OF APPEAL

2. ☐ The Notice of Appeal was filed on _____. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
(a) ☒ They raise new issues that would require further consideration and/or search (see NOTE below);
(b) ☒ They raise the issue of new matter (see NOTE below);
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
(d) ☒ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

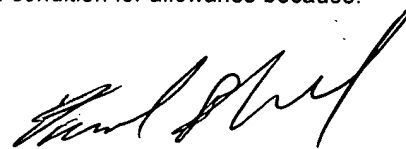
4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).
5. ☐ Applicant's reply has overcome the following rejection(s): _____.
6. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.
The status of the claim(s) is (or will be) as follows:
Claim(s) allowed: _____.
Claim(s) objected to: _____.
Claim(s) rejected: 25-39, 43-44 and 49-65.
Claim(s) withdrawn from consideration: _____.

AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing of good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

REQUEST FOR RECONSIDERATION/OTHER

11. ☐ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: _____.
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08) Paper No(s). _____.
13. ☐ Other: _____.



DAVID J. BLANCHARD
PATENT EXAMINER

Continuation of 3. NOTE: The reply filed 3/16/2007 raises new issue, requiring new considerations, new search and new rejections. The claims as presently amended recite that each of the first and second Fab' has a single hinge region cysteine residue and has a C terminal amino acid sequence of Cys-Ala-Ala, which is a limitation not previously presented, searched and fully considered. For example, entry of the amendment would require new grounds of rejections under 35 U.S.C. 112, second paragraph as being indefinite as it is unclear what is contemplated by each Fab' having a "single hinge region cysteine residue and has a C terminal amino acid sequence of Cys-Ala-Ala" because a single hinge region cysteine residue AND a C terminal sequence of Cys-Ala-Ala is two hinge cysteines. Is the Cys-Ala-Ala not part of the hinge? Further, entry of the amendment would raise the issue of new matter under 35 USC 112 first paragraph. For support of the present amendment, applicant points to pg. 30, lines 26-27 of the specification, which discloses a single hinge cysteine residue having the C terminal sequence Cys-Ala-Ala meaning that the single cysteine is the cysteine in the Cys-Ala-Ala sequence. In contrast the claims as presently amended recite a single hinge cysteine residue AND the C terminal sequence Cys-Al-Ala, which does not have adequate written support in the as filed specification as pointed to by applicant. Additionally, the amendment to claims 54 and 60 raise new issues. For example, as presently amended the claims recite a nucleic acid encoding a light chain variable domain, a heavy chain variable domain and a CH1 domain fused to one or more cysteines or a cysteine containing polypeptide for producing a Fab'. As defined in the art and in applicants' specification (pg. 11) a Fab' is a heterodimer of heavy and light chains, wherein the heavy chain comprises the variable domain and the first constant domain (i.e., CH1 domain) and the light chain comprises the variable domain and constant domain, plus at least one additional amino acid residue at the carboxy terminus of the heavy chain CH1 domain including one or more cysteine residues. The claims do not recite the light chain constant domain and while the heavy and light chains of the Fab' would form a heterodimer, they would not be encoded and are not disclosed as being encoded by a single nucleic acid molecule as currently claimed. Further, the amendment to claims 54 and 60 deletes the C terminal amino acid sequence Cys-Ala-Ala and as such the prior art already of record would have to be reapplied.

Respectfully,
David J. Blanchard
571-272-0827